



# Status of Leukoreduction Among ABC Member Centers

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# Questions from FDA

**What is the current proportion of LR products?**

# ABC Survey on Leukoreduction

## Units distributed Jan-Jun 2005

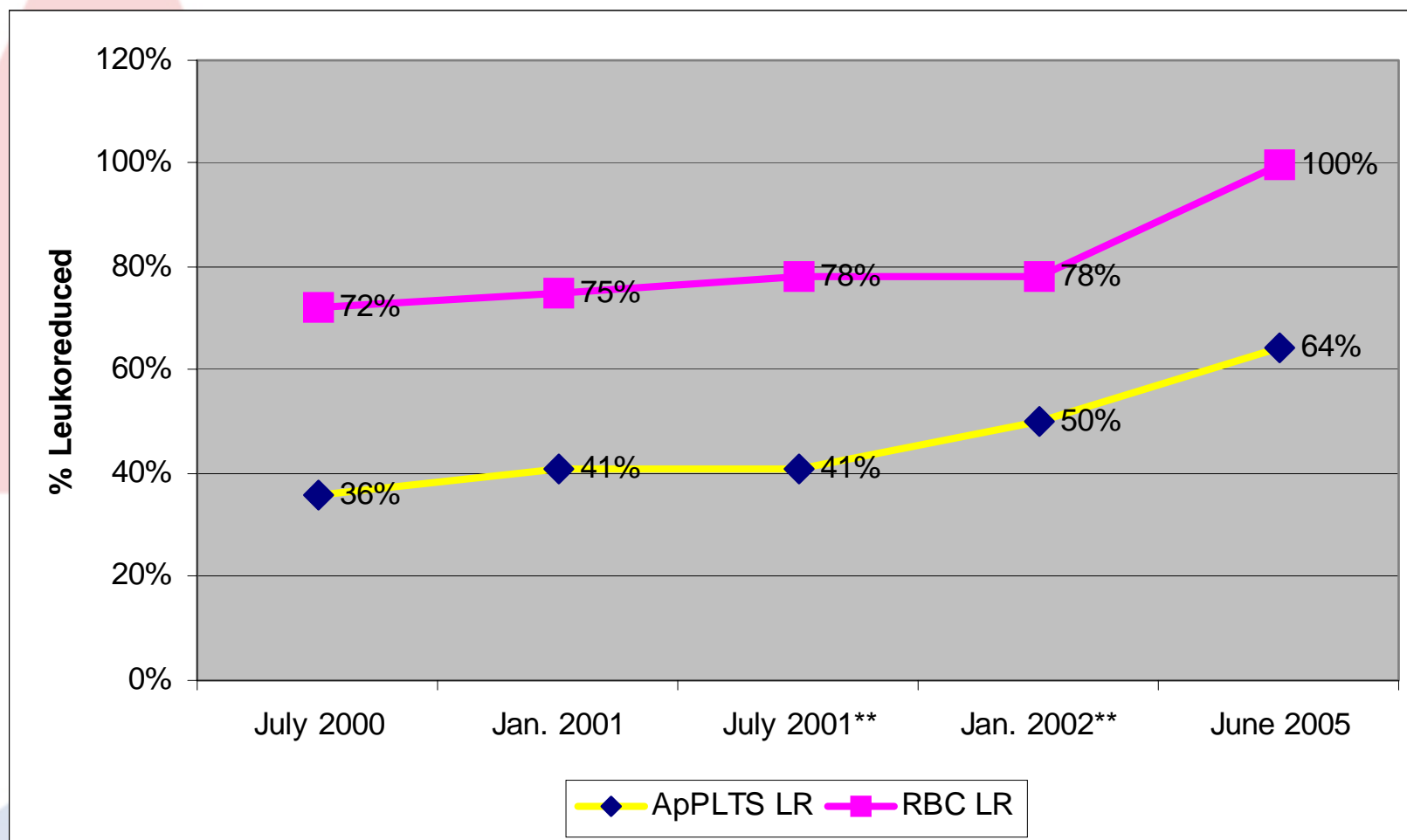
<b>Component</b>	<b>Number Leukoreduced</b>	<b>% Leukoreduced</b>
<b>RBC from Whole Blood</b>	<b>1,737,879</b>	<b>64%</b>
<b>RBC from Apheresis</b>	<b>285,012</b>	<b>94%</b>
<b>Platelets from Apheresis</b>	<b>325,163</b>	<b>100%</b>
<b>Platelets from Whole Blood</b>	<b>61,632</b>	<b>14%</b>

A large, stylized graphic of the American flag is positioned on the left side of the slide. It features a large red triangle at the top, a white triangle in the middle, and a blue triangle at the bottom, all with a slight 3D effect. The number '4' is located at the bottom left of the blue triangle.

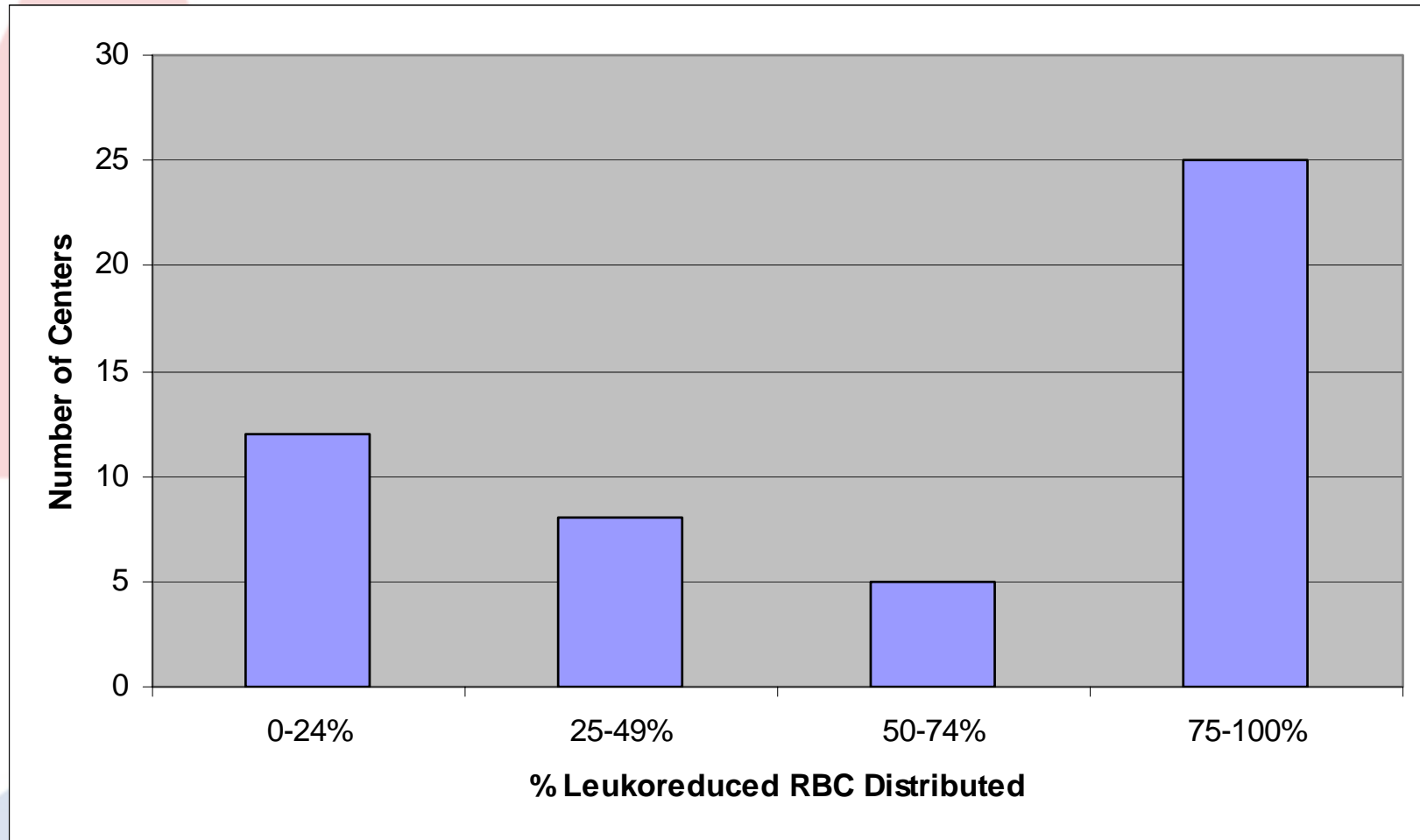
# Questions from FDA

**Is the trend based on customer demand upwards or downwards?**

# ABC Blood Components Distributed as Leukoreduced 2000-2005



# Distribution of ABC Member Centers According to % Leukoreduced RBC





# Questions from FDA

**What methods are currently being used for WBC counting... is there an increased use of automation?**

## Method Used for WBC Counting

Method	Number of Centers	% of Centers
Nageotte	21	42
Flow Cytometer	17	34
Imagn 2000	4	8
Outside lab	7	14





# Questions from FDA

**What proportion of units QC'd fail to meet the standards?**

# Units Submitted for QC

## Units *manufactured*

	RBC	Apheresis Platelets
Leukoreduced units	1,308,164	277,259
QC'd units	23,318 (1.78%)	15,183 (5.48%)
QC Failures	178 (0.76%)	91 (0.60%)



# Questions from FDA

**Are QC failures and filtration failures  
being investigated for cause...  
and if so, what are the causes?**

# Investigation of 5,683 Filter Failures

<b>Cause Not Identified</b>	<b>65%</b>
<b>Cause Identified</b>	<b>35%</b>
- Clogging, Clots	81%
- Stopped Due to Excessive Time	49%
- Sickle Cell Trait	32%
- Mechanical (Priming, Kinks)	2%
- Other	7%

# Questions from FDA

**Are automated blood collection mixers in place at most sites? Does their use correlate with reduced filtration failures**

**Preliminary analysis found no correlation.**